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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/354,500	07/16/1999	MACK J. SCHERMER	GSIL-0109-PU	5234
24267	7590	07/17/2006	EXAMINER	
CESARI AND MCKENNA, LLP 88 BLACK FALCON AVENUE BOSTON, MA 02210			ALLEN, MARIANNE P	
			ART UNIT	PAPER NUMBER
			1647	

DATE MAILED: 07/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.



### **DETAILED ACTION**

Applicant's arguments filed 1/19/06 and 5/8/06 have been fully considered but they are not persuasive.

#### ***Claim Rejections - 35 USC § 112***

Claims 1-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 1 and 10 have been amended to recite "computing a set of correction factors based on ratios." Basis is stated to be on pages 7-9. This is not agreed with. Pages 7-9 disclose a particular set of equations or type of computations. This is not considered to be a general disclosure for correction factors based on all ratios of output.

Claims 10-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In view of the means plus function language in claims 10-18 and applicant's express intent to invoke 35 USC 112, 6<sup>th</sup> paragraph (see response submitted 5/8/2006), claims 10-18 have been treated under 35 USC 112, 6<sup>th</sup> paragraph.

Claim 10 recites “means for measuring an output of each of the output channels,” “means for computing a set of correction factors,” and “means for applying the set of correction factors to quantitation data.”

When applicant invokes 35 USC 112, 6<sup>th</sup> paragraph, applicant must describe the structure in the specification and link the structure that corresponds to the recited function in the “means for” language. The specification must set forth adequate disclosure showing what is meant by the means plus function language such that one skilled in the art would have understood what structure will perform the recited function. The instant specification provides no such disclosure and does not link the structure and function. This duty to link or associate structure to function is the quid pro quo for the convenience of employing 112, paragraph 6.”); *Medical Instrumentation and Diagnostic Corp. v. Elekta AB*, 344 F.3d 1205, 1218, 68 USPQ2d 1263, 1268 (Fed. Cir. 2003).

Applicant points to Figures 7 and 8 and page 5, line 20, through page 6, line 18. Applicant argues that “means for computing” and “means for applying” are a workstation or any other general or special purpose computer. Applicant argues that “means for measuring an output” are a microarray reader or scanner. The specification, including Figures 7 and 8, do not set forth these concepts. The specification describes Figure 7 as a schematic diagram illustrating a preferred hardware configuration on which the computational portion of the method can be implemented. The specification describes Figure 8 as a schematic view of a system. The specification makes clear other configurations are possible. The specification does not identify the particular structure that performs each of the functions required by the means plus function language in the claims. The specification does not identify the structure responsible for

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“measuring an output of each of the output channels” as being a microarray reader or scanner.

The specification does not identify the structure responsible for both “computing a set of correction factors” and “applying the set of correction factors to quantitation data” as being a workstation or any other general or special purpose computer.

The specification lacks the corresponding structure as required by 35 USC 112, 6<sup>th</sup> paragraph, and fails to comply with 35 USC 112, second paragraph. “If one employs means plus function language in a claim, one must set forth in the specification an adequate disclosure showing what is meant by that language. If an applicant fails to set forth an adequate disclosure, the applicant has in effect failed to particularly point out and distinctly claim the invention as required by the second paragraph of section 112.” *In re Donaldson Co.*, 16 F.3d 1189, 1195, 29 USPQ2d 1845, 1850 (Fed. Cir. 1994) (in banc).

Applicant is reminded that when 35 USC 112, 6<sup>th</sup> paragraph, is invoked, the claims are limited to the structure described in the specification and equivalents thereof. As such, it must be clear what structures are intended.

Claims 10-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is an enablement rejection.

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If there is no link between structure and function as set forth above, one skilled in the art would not have known how to make and use the invention without a description of elements to perform the function.

Furthermore, the specification enables automatically creating crosstalk-corrected data of a microarray using the exemplified matrix algebra but does not reasonably provide enablement for computing a set of correction factors and applying the set of correction factor to quantitation data obtained from the generated microarray images in any other way. This portion of the rejection is maintained for reasons of record. The specification does not provide guidance on how to use other ratios of the output measurements to compute a set of correction factors to automatically create crosstalk corrected data of a microarray.

Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for automatically creating crosstalk-corrected data of a microarray using the exemplified matrix algebra, does not reasonably provide enablement for computing a set of correction factors and applying the set of correction factor to quantitation data obtained from the generated microarray images in any other way. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

This rejection is maintained for reasons of record. The specification does not provide guidance on how to use other ratios of the output measurements to compute a set of correction factors to automatically create crosstalk corrected data of a microarray.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 571-272-0712. The examiner can normally be reached on Monday-Thursday, 5:30 am - 1:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Marianne P. Allen  
Primary Examiner  
Art Unit 1647

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